REMARKS/ARGUMENTS

In the Office Action mailed October 9, 2009, claim 4 has been objected to, and claims 1-10, 13, 18-23, 26 and 28-29 stand rejected. Without conceding the propriety of these rejections, claims 1, 3, 5, 7-9, 18, 19, 21, 22, and 23 have been amended. Claim 1 has been amended to refer to an "isolated" polypeptide for which there is support at least at in page 5, lines 10 and 11 and page 12, lines 25 and 26 of the specification. Claim 3 has been amended to correct a typographical error. Claim 5 has been amended to refer to an "isolated" host cell for which there is support at least at page 18, lines 6 to 14 of the specification. Claims 5, 7, 8 and 9 have been amended to refer to a "nucleic acid" vector to be consistent with claim 4. Claim 18 is amended to define the antibody rather than depending from claim 10. Claim 19 is amended to define the polypeptide rather than being dependent from claim 1. There is support for this amendment at least in original claims 1 and 19. There is support for the reference to the "antigenic fragment" at least at page 5, lines 13, 14, 16 and 17 of the application. In claim 19, the term "isolated" is also removed where it relates to the antibody or antigen binding fragment. Claim 21 is amended to refer to an "antigen binding" fragment and an "isolated polypeptide" to be consistent with claims 10 and 1, respectively. Claim 22 is amended in an analogous manner to claim 18. Claim 23 is amended to replace the term "medicament" with the term "composition" to be consistent with claim 13.

Applicants have thoroughly reviewed the outstanding Office Action including the remarks and the references cited therein. The following remarks are believed to be fully responsive to the Office Action. All the pending claims at issue are believed to be patentable over the cited references.

SPECIFICATION OBJECTIONS

The Specification stands objected to as having hyperlinks. The Specification has been amended to remove the hyperlinks. Withdrawal of the objection is respectfully requested.

CLAIM OBJECTIONS

Claim 4 is objected to as being dependent on a rejected base claim. As described herein, the Applicants believe the amendments to claim 1 overcome the aforementioned rejection. Withdrawal of the objection is respectfully requested.

CLAIM REJECTIONS – 35 U.S.C. §101

Claim 1 stands rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. In the enclosed amended claims, claim 1 is amended to relate to "an isolated polypeptide" which the Examiner has acknowledged should overcome this rejection. Accordingly, Applicants respectfully submit that this claim is allowable.

CLAIM REJECTIONS – 35 U.S.C. §112

Claims 18-20, 22 and 26 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Without conceding to the propriety of this rejection, claims 18, 19 and 22 have been amended so that they now relate to a polypeptide with the sequence of SEQ ID NO: 2 (i.e., 100% sequence identity) or an antibody thereto. Claim 19 also refers to "an isolated

antigenic fragment of a polypeptide consistent with SEQ ID NO: 2". However, the sequence of SEQ ID NO: 2 is disclosed in the specification and therefore no additional or different amino acids are required in order to generate antigenic fragments of the polypeptide of SEQ ID NO: 2. Accordingly, Applicants respectfully submit that these claims are allowable.

Claim 5 stands rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Amended claim 5 enclosed herewith has been amended to relate to "an isolated host cell" which the Examiner has indicated will obviate the rejection. Accordingly, Applicants respectfully submit that this claim is allowable. .....

Claims 5, 7-9, 18-23 and 26 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully submit that the amendments to claims 5, 7-9, 18-23 obviate the foregoing rejections. Accordingly, Applicants respectfully submit that these claims are allowable. .....

CLAIM REJECTIONS – 35 U.S.C. §102

Claims 1 and 28 stand rejected under 35 U.S.C. §102(b) as being anticipated by Cerquetti *et al.* (1992 *Microbial Pathogenesis*, Vol. 13, pgs. 271-279; "Cerquetti"), as evidenced by Wright *et al.* (2005 *Proteomics*, Vol. 5, pgs. 2443-2452; "Wright"). In light of the following remarks, Applicants respectfully submit that these claims are allowable. .....

Firstly, although the title and abstract of Cerquetli refer to a "36 kDa antigen" the exact molecular weight of the protein component of the antigen was not categorically established. It is stated in the paragraphs in pages 273 and 274 of Cerquetti that "Carbohydrate accounted for 9% of the purified protein on a weight base" thus indicating that the protein component of 36 kDa antigen was actually significantly less than 36 kDa. The subsequent test to confirm these results (see page 274, first paragraph of Cerquetti) failed so the molecular weight of the protein component of the antigen was not conclusively established. Nevertheless, it is consistent with at least some of the results from Cerquetti that the protein components of the antigen had a molecular weight of around 32.8 kDa (i.e., 36 kDa - 9% by weight).

As inspection of Table 2 of Wright will reveal, there are, in fact, several other proteins which have a molecular weight consistent with the antigen reported by Cerquetti, aside from lactate dehydrogenase. For example, glyceraldehyde-3-phosphate dehydrogenase has a molecular weight of 36015 Da (see Spots L 19, L20 and L37 in Table 2 of Wright and ABC transporter substrate binding protein (Spot L33 in Table 2) has a molecular weight of 36049 Da. Furthermore, since the molecular weight of the antigen in Cerquetti was only estimated by SDS-PAGE, it would not be unreasonable to conclude that the antigen could have been a *C. difficile* protein having a theoretical molecular mass slightly above or below 36 kDa, such as EtfA 1, electron transport flavo-protein (see Spot L24 in Table 2 of Wright which has a theoretical molecular mass of 37129 Da.

Moreover, since, as explained above, the protein components of the 36 kDa antigen of Cerquetti may have been around 32.8 kDa, it might instead correspond to glyceraldehyde-3-phosphate dehydrogenase (see Spot L20 in Table 2) with a theoretical molecular mass of 32647

Da; CysK cysteime synthase (Spot L32 in Table 2) with a theoretical molecular mass of 32647 Da; or nitroreductase (Spot L46 in Table 2) with a theoretical molecular mass of 32711 Da.

It is also notable that the isoelectric point of the 36 kDa antigen reported by Cerquetti was found to be 4.6 (see the abstract and page 273, second paragraph of Cerquetti.) In contrast, Wright reported that the theoretical isoelectric point of *C. difficile* lactate dehydrogenase is 5.1. There is a significant difference between a PI of 4.6 and 5.1, bearing in mind that the scale is logarithmic. Therefore, the reference to Wright actually teaches away from the conclusion that the 36 kDa antigen of Cerquetti was *C. difficile* lactate dehydrogenase and is therefore precluded from use as a reference. See M.P.E.P. 2145(D)(2).

In fact, there are many other proteins reported in Table 2 of Wright which have a PI closer to 4.6 than lactate dehydogenase does. For example, the unidentified protein of Spot L36, elongation factor Tu (Spot 48) and HMWUSLP (Spots L56 and L57) all have a theoretical PI of 4.6. Indeed, it is notable that EtfA1, electron transport flavo protein (Spot L24 of Table 2) has a theoretical PI of 4.6 and a theoretical molecular mass of 37129 Da and therefore more closely fits the data from Cerquetti et al than does lactate dehydrogenase.

Thus, taken overall, it cannot be said that Wright demonstrates that the 36 kDa antigen of Cerquetti was *C. difficile* lactate dehydrogenase. Other proteins such as EtfA 1, electron transport flavo protein have a molecular mass and PI which, together, more closely fit the observed characteristics of the antigen identified by Cerquetti.

For these reasons, the Applicants respectfully dissagree that the 36 kDa polypeptide of Cerquetti is the same as the polypeptide of SEQ ID NO:2 of the present invention and therefore Cerquetti does not anticipate the polypeptide of claims 1 and 28 of the pending claims.

CLAIM REJECTIONS – 35 U.S.C. §103

Claims 1-3, 10, 21 and 28-29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cerquetti and Campbell (Chapter 1, pg. 1, *Monoclonal Antibody Technology* pgs. 3-5, 1984) as evidenced by Wright. In light of the following remarks, Applicants respectfully submit that these claims are allowable.

As already described hereinabove, the reference to Wright actually teaches away from the conclusion that the 36 kDa antigen of Cerquetti was *C. difficile* lactate dehydrogenase and is therefore precluded from use as a reference. See M.P.E.P. 2145(D)(2). In addition, the Examiner has asserted that, although Cerquetti does not teach an isolated nucleic acid molecule, "Campbell teach when a protein has been identified one would want to generate antibodies to isolate a gene (see page 23, column 2, page 24, column 1)." However, a review of these passages in Campbell provides no suggestion or teaching that one would generate antibodies to isolate a gene. Therefore, even if it could be accepted that Cerquetti disclosed the lactate dehydrogenase protein of SEQ ID NO: 2 of the present application, this in no way establishes that it would be obvious to isolate antibodies to isolate the gene encoding the polypeptide. It is notable that Cerquetti does not disclose the function or amino acid sequence of the protein component of the 36 kDa antigen. It is not seen that there is any teaching in Campbell that would teach a skilled person to obtain the nucleic acid sequence from an antigen, under such circumstances. The Examiner asserts that generating antibodies to the antigen would allow a skilled person to achieve this but it is not seen how this would assist the skilled person since an antibody would only allow a skilled person to isolate the antigen but, in fact, the antigen is already isolated as reported in Cerquetti.

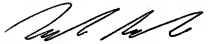
In view of the foregoing, withdrawal of the 35 U.S.C. §103(a) rejection to claims 1-3, 10, 21 and 28-29 as being anticipated by Cerquetti and Campbell as evidenced by Wright is respectfully requested.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request that all the objections and rejections to the claims be removed and that the claims pass to allowance. If, for any reason, the Examiner disagrees, please call the undersigned at 202-861-1629 in an effort to resolve any matter still outstanding before issuing another action. The undersigned is confident that any issue which might remain can readily be worked out by telephone.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiencies or credit any overpayments to Deposit Account No. 50-2036 with reference to our Docket No. 87278.2740.

Respectfully submitted,
BAKER & HOSTETLER LLP



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